FR Doc #04-7985
Public Comment #500010

PRESIDENT'S DEPARTMENT
AIR LINE PILOTS ASSOCIATION, INTERNATIONAL
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June 14, 2004

VIA FACSIMILE to 301-443-3031 and
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Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, Maryland 20857

Re: FR Doc. 04-7985

Dear Sir or Madam:

These comments are submitted in response to the above-referenced revised Mandatory Guidelines for Federal Workplace Drug Testing Programs on behalf of the Air Line Pilots Association ("ALPA"), the principal union representing the nation's commercial pilots. ALPA represents more than 64,000 pilots at 42 airlines in the United States and Canada.

While ALPA maintains its objections to mandatory validity testing as stated in our prior comments to HHS in this rulemaking proceeding (October 22, 2001), we are glad to see that many of the serious concerns we have previously raised both to HHS and to the Department of Transportation ("DOT") have been addressed and incorporated in these mandatory guidelines. We appreciate and recognize the importance of the inclusion of the following protections in the final guidelines: (1) the employee right to split sample analysis of results reported as adulterated or "substituted" (using confirmation not screening tests) with cancellation of the result if not confirmed by the split analysis; (2) the requirement that MROs have applicable subject matter expertise; (3) MRO review of validity test results to determine whether such result can be explained by a legitimate medical explanation; (4) recognition that some individuals produce ultra-dilute urine and, as a result, lowering the creatinine cutoff from ≤ 5.0 to ≤ 2.0 mg/dL before a specimen can be reported as "substituted;" (5) the requirement to calibrate at 2.0 mg/dL for tests measuring creatinine; (6) the requirement for specimen validity testing controls at specified levels above and below each cutoff; (7) the requirement for confirmation by a second test, using a different methodology than the screening test, before any specimen is permitted to be reported as "adulterated;" and (8) the requirements for quality control and oversight of validity testing including but not limited to blind quality control specimens, proficiency tests under the national laboratory certification program, and the imposition of validity testing performance standards.

It is extremely troubling, however, that many of these protections were incorporated in the procedures only after innocent employees had been wrongly identified as rule violators. Some of these employees have been able to regain jobs only after substantial expenditures of time and money, while others' careers remain terminated. We strongly urge that the requirements of the rule be made retroactive, and that individuals with prior test results reported as adulterated or "substituted" be given a right to have those results cancelled upon a showing that such testing failed to comply with these regulatory standards.

While the mandatory guidelines contain many vital protections, some additional items should be addressed. First, it should be recognized that there is no scientific basis (or complete accord within the scientific community as shown at the Tampa meeting in February 2003) for identifying urine with creatinine less than 2.0 mg/dL as "substituted." DOT and SAMHSA were wrong in their prior claims that specimens with creatinine reported as less than 5.0 mg/dL could not be "human" urine, and ALPA so contended in numerous comments submitted over a period of years. Only after being forced to grapple with the claims and evidence from affected employees with ruined careers as well as the persistent critique of scientists, did the government finally alter that arbitrary standard. HHS should now recognize that 2.0 mg/dL is not a magic number below which individual wrongdoing is proven. To the contrary, data provided to HHS in October 2001 by the Association of Flight Attendants clearly demonstrated that in a sampling taken for an air quality study in 1998 and 1999 -- wholly unrelated to any drug testing issues or concerns -- two samples out of 85 tested had creatinine levels of 1.9 mg/dL and specific gravity of 1.001. (Attachment A hereto). This actual data evidences the real risk that employees face when treated as rule violators merely because their body produces urine that is more dilute than an arbitrary government cutoff level.

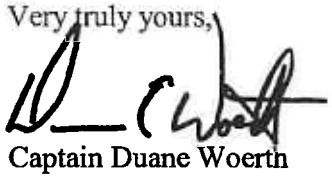
It should also be recognized that all tests, including those for creatinine, have a margin of error. HHS's proficiency testing permits a margin of error of $\pm$20% or $\pm$2 standard deviations. See Section 3.19, 69 Fed. Reg. 19669 (Apr. 13, 2004). Thus, if a known proficiency specimen of 2.2 mg/dL reported a result of 1.8 mg/dL it would satisfy the requisite performance standards. Likewise, the same equipment could report an employee's actual creatinine level of 2.2 mg/dL at 1.8 mg/dL, thus causing that person to be deemed a rule violator with the risk of loss of their career and livelihood. Such a result would be grossly unfair, and should be prevented.

In the face of the actual data demonstrating that unsuspecting individuals have creatinine as low as 1.9 mg/dL, the absence of any scientific support for an absolute cutoff, and in light of the grave harm suffered by real individuals who produce urine below the agency cutoff, we strongly urge that HHS's approach be reconsidered. Individuals whose creatinine is below 2.0 mg/dL should not be branded as wrongdoers but rather could be directed to submit to an immediate or subsequent unannounced, observed urine collection. Certainly, at a minimum, individuals whose creatinine level is reported below 2.0 mg/dL should have the right to provide medical evidence to exonerate themselves, a right that should be made explicit in the final regulations.

The final guidelines do not provide for a true confirmation test either of creatinine or specific gravity, but rather seek to use the specific gravity test as a confirmation of urine dilution. A more scientifically defensible approach would be to confirm urine dilution by measuring the osmolality of the specimen. Osmometers are one means of measuring urine dilution that is widely and generally accepted by the scientific community.

The final guidelines require the measurement of specific gravity to four decimal places. Requiring a greater degree of accuracy in such measurements would enhance the reliability of the reported results. The validity of the reported results would only be enhanced if specific gravity is an adequate way of measuring urine diluteness. The electronic refractometers used for such testing should first be evaluated by clinical studies to determine whether they have the requisite performance capability. Such study should be done prior to the use of that equipment for the broad scale employee specimen analysis required by this rule.

Very truly yours,



Captain Duane Woerth
President